DEC 1 2 2003

8. 510(k) SUMMARY

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Assigned 510(k) number is K033299.

Submitter:

ACON Laboratories, Inc.
4108 Sorrento Valley Boulevard
San Diego, California 92121

Tel.: 858-535-2030
Fax: 858-535-2038

Date:

October 7, 2003

Contact Person:

Edward Tung, Ph.D.

Product Names:

ACON® mAMP-500 One Step Methamphetamine Test Strip
ACON® mAMP-500 One Step Methamphetamine Test Device

Common Name:

Immunochromatographic test for the qualitative detection of Methamphetamine in urine.

Regulation Name:

Methamphetamine test system.

Product Code:

LAF

Classification Number:

21 CFR, 862.3610

Device Classification:

The Methamphetamine test systems have been classified as Class II devices with moderate complexity. The ACON mAMP-500 One Step Methamphetamine Test Strip and ACON mAMP-500 One Step Methamphetamine Test Device are similar to another FDA-cleared device for the qualitative detection of Methamphetamine in urine specimens. These tests are used to provide only a preliminary analytical result. All positive test results obtained with these devices must be confirmed by another test method, preferably GC/MS analysis.

Intended Use:

The ACON mAMP-500 One Step Methamphetamine Test Strip and ACON mAMP-500 One Step Methamphetamine Test Device are rapid chromatographic immunoassays for the qualitative detection of Methamphetamine in urine at a cutoff concentration of 500 ng/mL. These tests are used to provide only a preliminary analytical result. All positive test results obtained with these devices must be confirmed by another test method, preferably GC/MS analysis. They are intended for healthcare professionals including professionals at point-of-care sites.

Description:

The ACON mAMP-500 One Step Methamphetamine Test Strip and ACON mAMP-500 One Step Methamphetamine Test Device are competitive binding, lateral flow immunochromatographic assays for the qualitative screening of Methamphetamine in a urine sample. The test is based on the principle of antigen-antibody immunochemistry. It utilizes the mouse monoclonal antibody to selectively detect elevated levels of Methamphetamine and its metabolite in urine at a cutoff concentration of 500 ng/mL. These tests can be performed without the use of an instrument.

A drug-positive urine specimen will not generate a colored-line in the designated test region, while a negative urine specimen or a urine specimen containing Methamphetamine at the concentration below the cutoff level will generate a colored-line in the test region. To serve as a procedural control, a colored-line should always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

Comparison to a Predicate Device:

A comparison of the features of the ACON mAMP-500 One Step Methamphetamine Test Strip and ACON mAMP-500 One Step Methamphetamine Test Device versus a FDA-cleared Methamphetamine test with 500 ng/mL Methamphetamine cutoff is shown below:

- Both tests are assays intended for the qualitative detection of Methamphetamine in urine samples.
- Both tests are intended as a screening method that provides a preliminary analytical test result.
- Both tests are immunochromatographic, lateral flow assays for the rapid detection of Methamphetamine with a visual, qualitative end result.
- Both tests utilize the same basic immunoassay principles that rely on antigen/ antibody interactions to indicate a positive or negative result.
- Both tests have a cutoff Methamphetamine concentration of 500 ng/mL.

Safety and Effectiveness Data:

Accuracy

A clinical evaluation was conducted using 300 clinical urine specimens including approximately 10% of the specimens containing Methamphetamine concentration fell between –25% cutoff to +25% cutoff range. This evaluation compared the test results between ACON mAMP-500 One Step Methamphetamine Test Strip and ACON mAMP-500 One Step Methamphetamine Test Device with a FDA-cleared Methamphetamine test; as well as compared against data obtained from the customary Gas Chromatography/Mass Spectrometry analysis. These comparisons of data yielded the following results:

ACON mAMP-500 One Step Methamphetamine Test Strip versus a FDA-cleared mAMP 500 Test:

Positive Agreement: 108 / 108 = >99% (97 % - 100 %*)
Negative Agreement: 153 / 192 = 80% (73 % - 85%*)
Overall Agreement: 261 / 300 = 87% (83 % - 91 %*)
* 95% confidence intervals

ACON mAMP-500 One Step Methamphetamine Test Device versus a FDA-cleared mAMP 500 Test:

Positive Agreement: 108 / 108= 100% (97 % - 100 %*)
Negative Agreement: 158 / 192= 82% (76 % - 87 %*)
Overall Agreement: 266 / 300 = 89% (84 % - 92 %*)
* 95% confidence intervals

ACON mAMP-500 One Step Methamphetamine Test Strip versus data obtained with GC/MS at the cutoff concentration of 500 ng/mL:

ACON mAMP-500 One Step Methamphetamine Test Strip versus GC/MS

		Specimen Cutoff Range by GC/MS Data					% Agreement with GC/MS Data
		Negative	< -25% Cutoff	-25% to Cutoff	Cutoff to +25%	> +25% Cutoff	
ACON mAMP 500 Test Strip	Positive	0	0	7	8	132	100% (140/140) (97% - 100%)*
	Negative	150	0	3	0	0	97% (153/160) (91% - 98%)*

Total agreement with GC/MS : 293/300 = 98% (95%- 99%)*
* Denotes 95% confidence intervals.

ACON mAMP-500 One Step Methamphetamine Test Device versus GC/MS

		Specimen Cut off Range by GC/MS Data					% Agreement with GC/MS Data
		Negative	< -25% Cutoff	-25% to Cutoff	Cutoff to +25%	> +25% Cutoff	
ACON mAMP-500 Test Device	Positive	0	0	4	8	131	99% (139/140) (96% - 99%)*
	Negative	150	0	6	0	1	98% (156/160) (94% - 99%)*

Total agreement with GC/MS : 295/300 = 98% (96% - 99%)*
* Denotes 95% confidence interval.

Performance Characteristics and Other information:

The performance characteristics of ACON mAMP-500 One Step Methamphetamine Test Strip, ACON mAMP-500 One Step Methamphetamine Test Device were verified by analytical sensitivity study, specificity and cross reactivity study, interference studies, precision study, read time flex study, temperature flex study, specimen storage and stability study. Study results indicate that these test devices are robust and can perform satisfactorily when used according to the "Indication for Use" statement specified in their package inserts.

Conclusion:

These clinical studies demonstrated substantial equivalency on performance between the ACON mAMP-500 One Step Methamphetamine Test Strip, ACON mAMP-500 One Step Methamphetamine Test Device and a FDA-cleared Methamphetamine test with the same Methamphetamine cutoff concentration. It is also demonstrated that these tests are safe and effective in qualitatively detecting Methamphetamine at a concentration of 500 ng/mL. The POL study demonstrated that these tests are suitable for healthcare professionals including professionals at point-of-care sites.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 12 2003

Edward Tung, Ph.D.
Regulatory Affairs
ACON Laboratories, Inc.
4108 Sorrento Valley BLvd.
San Diego, CA 92121

Re: k033299
Trade/Device Name: ACON mAMP-500 One Step Methamphetamine Test Strip
ACON mAMP-500 One Step Methamphetamine Test Device
Regulation Number: 21 CFR 862.3610
Regulation Name: Methamphetamine test system
Regulatory Class: Class II
Product Code: LAF
Dated: October 7, 2003
Received: October 14, 2003

Dear Dr. Tung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Recd
12-10-03

11. INDICATIONS FOR USE

510(k) Number: K033299

Device Name: ACON mAMP-500 One Step Methamphetamine Test Strip

ACON mAMP-500 One Step Methamphetamine Test Device

Indications for Use:

The ACON® mAMP 500 One Step Methamphetamine Test Strip and Test Device are rapid immunochromatographic assays for the qualitative detection of methamphetamine, a central nervous stimulating drug, in urine. Measurements obtained by these devices are used in the diagnosis and treatment of methamphetamine use or overdose.

This assay provides only a preliminary result. In order to obtain a confirmed analytical result, a more specific alternate chemical method is needed. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmation method.

Division Sign-Off for Jean Cooper

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K033299

Prescription Use ✓ Over the Counter —